K032088

1/2 AUG - 1 2003

510(k) Premarket Notification Summary of Safety and Effectiveness Information	*ThermaCool TC SYSTEM* July 3, 2003

Device Name: **ThermaCool TC System**
Common Name(s): RF Unit, coagulator
Classification Name: Electrosurgical cutting and coagulation device and accessories

Establishment Name & Registration Number:
Name: Thermage
Number: 2954746

Classification:
Title 21, Code of Federal Regulations,

§ 878.4400 Electrosurgical cutting and coagulation device and accessories. (a) Identification. An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current. (b) Classification. Class II.

ProCode: 79GEI

Equivalent Device(s):
The modified ThermaCool TC System claims substantial equivalence to the ***ThermaCool TC System K013639*** and ***K021402***.

Description of the Device:

The device as described in the above referenced Premarket Notifications has been modified to include a modified Skin Marking Paper.

Applicant / Sponsor Name / Address:
Thermage
4058 Point Eden Way
Hayward, CA 94545-3721
510.782.2286 telephone
510.782.2287 fax

Contact Person:
Pamela M. Buckman, R.N., M.S.
Thermage
4058 Point Eden Way
Hayward, CA 94545-3721
510.782.2286 telephone
510.723.3348 fax

Submission Correspondent:
Pamela M. Buckman, R.N., M.S.
Thermage
4058 Point Eden Way
Hayward, CA 94545-3721
510.782.2286 telephone
510. 723.3348 fax

K032088 2/2

Manufacturing Facility:
At the present time, this ***ThermaCool TC System accessory*** is manufactured by Thermage Inc. in accordance with defined Thermage specifications.

Performance Standards:
There are no applicable FDA mandated performance standards for electrosurgical cutting and coagulation device and accessories. However, voluntary standards such as in-house Standard Operating Procedures and QSR based vendor qualification procedures are in place and utilized in the production of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Ms. Pamela Buckman, R.N., M.S.
Vice President Clinical/Regulatory Affairs
Thermage
4058 Point Eden Way
Hayward, California 94545-3721

Re: K032088
Trade/Device Name: ThermaCool TC System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 3, 2003
Received: July 15, 2003

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER: K032088

DEVICE NAME: ThermaCool TC System

INDICATIONS FOR USE:

The ThermaCool TC System is indicated for use in

- Non-invasive treatment of periorbital rhytids and wrinkles
- Dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032088

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)